Remarks

Applicants have received and reviewed the Office Action dated December 3, 2009. Applicants request entry of this Amendment and reconsideration of the rejection of the claims. Claim 1 has been amended. The amendment to claim 1 is supported throughout the specification including at page 5, line 26 to page 6, line 10.

Interview summary

Applicants thank Examiner Treyger for the interview conducted on May 21, 2010. We discussed the 112 and 103 rejections of record. Applicants distinguished the claimed subject matter from the cited references by structural and functional differences.

35 U.S.C. § 112

Claims 1-4, 8 and 10-13 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. While not acquiescing to the rejection and solely to expedite prosecution, Applicants have amended claim 1 to address the rejection. Applicants request withdrawal of this rejection.

35 U.S.C. § 103(a)

Claims 1-4, 8 and 10-13 were rejected under 35 U.S.C. § 103(a) over Rockey, US 4,763,653 in view of Stack et al., US 2003/0199991. Applicants traverse this rejection.

The recent Supreme Court case, *KSR Int 'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007), sets forth the legal standard for obviousness. This case reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. Id. at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others may also be persuasive.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Id.* at 1445. Obviousness is then determined on the basis of the

evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445. One criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

"It remains important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). "Hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant's claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The claimed subject matter is nonobvious if it involves a number of complex and unpredictable alternatives and there is no reason one of skill in the art would select one alternative over another. *Ortho-McNeil vs. Mylan, Inc*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Applicants' claim 1 is directed to an implantable gastro-intestinal device comprising: a gastric bypass comprising an inlet and an outlet and comprised of a permeable material; an inflatable chamber comprising an expandable toroidal like chamber larger on one side as compared to the other side, and attached to the exterior of the gastric bypass and located proximate to the inlet of the gastric bypass, wherein the toroidal like chamber holds the inlet in an open configuration when the toroidal chamber is inflated; an esophageal extension comprising one or more flaps, and attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; a small bowel extension attached to the outlet of the gastric bypass and comprised of a permeable material, wherein the small bowel extension receives material exiting the outlet of the gastric bypass.

Applicants submit that the combination of the references does not disclose all of the elements of the claims and there would be no reasonable expectation of success of obtaining the claimed subject matter from the combination of the references.

The Rockey et al. reference does not disclose all of the elements of the claims, and differs structurally from the claimed subject matter. The Figure 9 referenced by the Examiner refers to a intravascular device for removing plaque. The device of Rockey does not disclose a sleeve made of permeable material. The sleeve of Rockey cannot be permeable because it could then allow blood to leak out. Secondly, the inflatable chamber in the device of Rockey is not attached to the sleeve as it is removed form the sleeve and is only used to press the sleeve against the blood vessel wall. Thirdly, the inflatable chamber of Rockey is not toroid like and is not attached to the exterior of the sleeve. The inflatable chamber of Rockey must be inside the sleeve in order to push the sleeve against the blood vessel wall.

The deficiencies of Rockey are not remedied by reference to Stack. Stack also does not describe a device that is made of a permeable gastric sleeve. Stack describes reservoir for drugs that are permeable but indicates that the gastric bypass is not permeable. Stack states at para 0038:

> "By preventing food from contacting the antrum walls as it passes form midstomach to the pylorus, the device prevents the modulation of Ghrelin or other satiety controlling factors."

and at para 0075:

> "For example, it may be formed of self-expandable material such as nitinol, stainless steel, or shape memory polymer(e.g. olig-(caprolactone)-dimethylacrylate or n-butyl acrylate) and covered with a polymer covering that is resistant to gastric juices(e.g. silicone) and that prevents passage of food byproducts through the walls of the tube."

Thus, combining Rockey and Stack does not provide for a gastric sleeve comprised of permeable material.

Secondly, the inflatable chamber in the device of Rockey is not attached to the sleeve as it is removed form the sleeve and is only used to press the sleeve against the blood vessel wall. Even if this device was employed in the gastrointestinal tract, there would be no reason to attach

the inflatable chamber to the sleeve because Rockey et al. teach that the sleeve has liquid that solidifies into a semi rigid shape preventing collapse of the sleeve and that the balloon is removed. See column 6 lines 64 to column 7, line 2.

Thirdly, the inflatable chamber of Rockey is not toroid like and is not attached to the exterior of the sleeve. There would be no reason to modify the inflatable chamber of Rockey to a toroid like shape that is larger on one side because the purpose of the chamber in Rockey is different than that of the claimed subject matter. In Rockey, the sleeve is held against the vessel wall by the liquid within the sleeve that forms a semi rigid wall and there would be no reason to have the chamber larger on one side as compared to the other side. The inflatable chamber of Rockey needs to be interior to the sleeve in order to expand the sleeve to the vessel wall and then be removed. In contrast, with regard to Applicants' subject matter, the purpose of the inflatable chamber is to hold the inlet open, prevent twisting of the gastric sleeve and to provide a satiety structure.

In addition, Stack does not describe an inflatable chamber that is toroid like and larger on one side as compared to the other side. Stack describes devices that expand to fill the entire space and contact the wall of the stomach. There is no description in Stack that an inflatable chamber that is toroid like can or should be employed. In addition, there is no teaching or suggestion in Stack that such an inflatable chamber is located proximal to the inlet and can serve to hold the inlet open as well as prevent twisting of the gastric sleeve. Since the devices of Stack expand to the stomach wall there is no need to have a chamber that would hold the inlet open or that prevents twisting of the gastric sleeve.

There would be no reason to combine the teaching of these references or a reasonable expectation of success. The device of Figure 9 of Rockey et al. is an intravascular device to remove plaque. The sleeve in Rockey et al. is not permeable as this could cause blood to leak out of the device and dislodge it from the blood vessel. Moreover, even if the device was applied into the gastrointestinal tract, according to Stack, it would not be made of permeable material because Stack teaches that it is not desirable to have food contact the stomach wall and modulate ghrelin production.

Secondly, the inflatable chamber in Rockey et al. is used to expand the sleeve against the blood vessel wall and is not attached to the sleeve because it is removed once the sleeve is in place. Even if this device was employed in the gastrointestinal tract, there would be no reason to attach the inflatable chamber to the sleeve because Rockey et al. teach that the sleeve has liquid that solidifies into a semi rigid shape preventing collapse of the sleeve and that the balloon is removed. See column 6 lines 64 to column 7, line 2. There would be no reason to combine any of the structures of Stack with those of Rockey et al. because the inflatable chamber of Rockey is removed and the sleeve is maintained against the vessel wall by a different mechanism. Leaving the inflatable chamber in the device of Rockey could be detrimental in terms of narrowing the passage way of blood or food through the sleeve.

Thirdly, Rockey et al. do not describe a device having a toroid like inflatable chamber larger on one side as compared to the other side or attached to the exterior to the sleeve. There would be no reason to modify the inflatable chamber of Rockey to a toroid like shape because the purpose of the chamber in Rockey is different than that of the claimed subject matter. In Rockey, the sleeve is held against the vessel wall by the liquid within the sleeve that forms a semi rigid wall. The inflatable chamber of Rockey needs to be interior to the sleeve in order to expand the sleeve to the vessel wall and then be removed. There would be no reason to combine any of the structures of Stack with those of Rockey et al. because the inflatable chamber of Rockey is removed and the sleeve is maintained against the vessel wall by a different mechanism. Placing the inflatable chamber exterior to the sleeve of Rockey would be detrimental to removing the inflatable chamber and/or to allowing the sleeve to solidify against the wall.

Thus, Applicants request withdrawal of the rejection on this basis.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,
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Date: May 24, 2010

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